

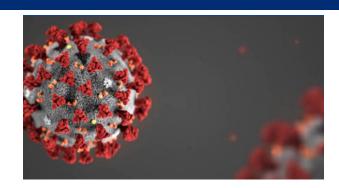
An Update for NYS Healthcare Providers on COVID-19

July 2, 2020

Elizabeth Dufort, MD, FAAP
Medical Director, Division of Epidemiology
New York State Department of Health

Agenda

- Global, National, New York State Updates
- Testing Updates
- Travel Advisory
- Community Mitigation and Reopening
- Treatment Updates
- MIS-C
- Vaccines
- Travel advisory in healthcare
- Healthcare Provider Wellness
- Resources
- Pre-planned Q & A: Chat box not feasible with level of attendance _





 Recordings will be available immediately: NYSDOH COVID-19 Healthcare Provider website

 In addition to YouTube, an on-demand version of our weekly sessions for healthcare providers in NYS is now available as a podcast – search NYSDOH



Disclaimer

 The situation is rapidly evolving, as is our understanding of this new virus.

 All of the information presented is based on our best knowledge as of today.



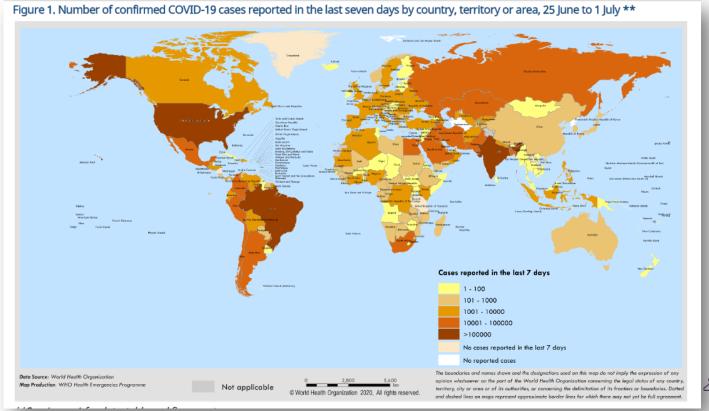
Situation Summary: COVID-19 Global, 7/1/2020

www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

Region	Confirmed Cases	Deaths
Global	10,357,662	508,055
Western Pacific	217,146	7,453
European	2,728,059	197,874
South-East Asia	808,906	22,253
Eastern Mediterranean	1,077,426	24,970
Africa	306,794	6,192
Americas	5,218,590	249,318

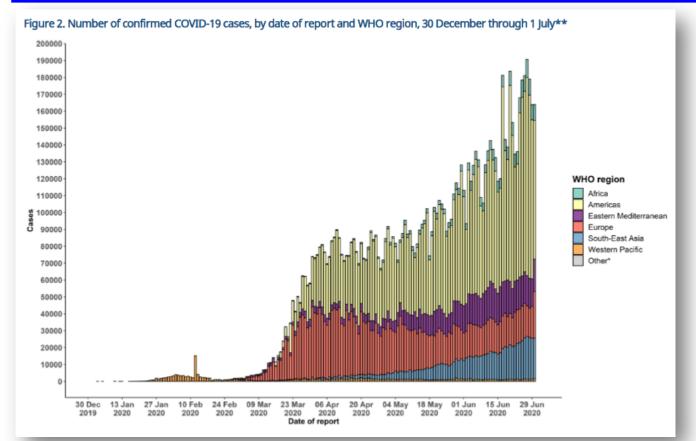


Situation Summary: COVID-19 Global, 7/1/2020 www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports





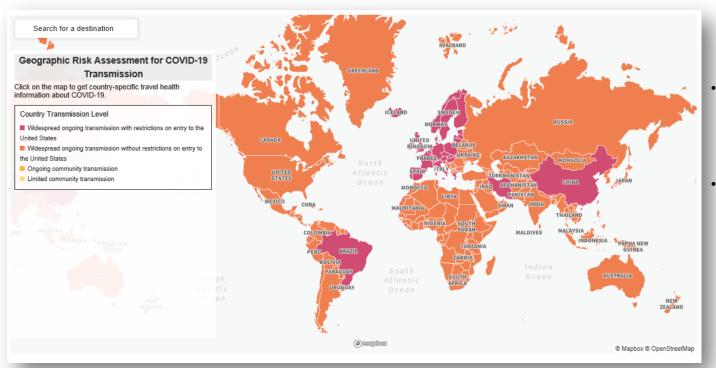
Situation Summary: COVID-19 Global, 7/1/2020 www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports





COVID-19 CDC Travel Recommendations by Country

https://www.cdc.gov/coronavirus/2019-ncov/travelers/map-and-travel-notices.html

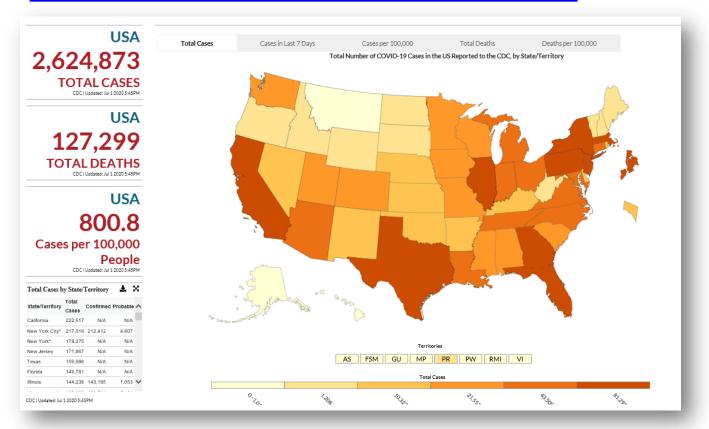


transmission with US entry restrictions: Brazil, China, Iran, Most of Europe, UK and Ireland Level 3 Widespread transmission without US entry restrictions: Global

Pandemic



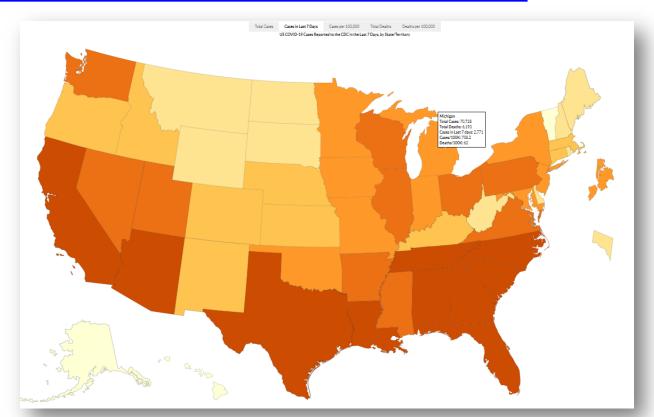
CDC COVID Data Tracker (July 1, 2020)



- New cases since
 6/30: 43,644
- New deaths since
 6/30: 560

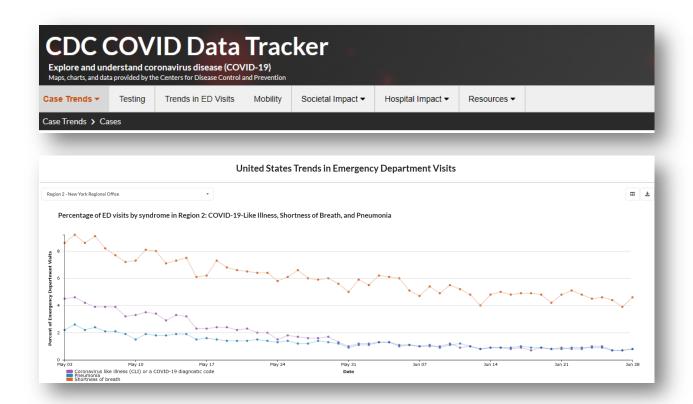


CDC COVID Data Tracker (July 1, 2020)



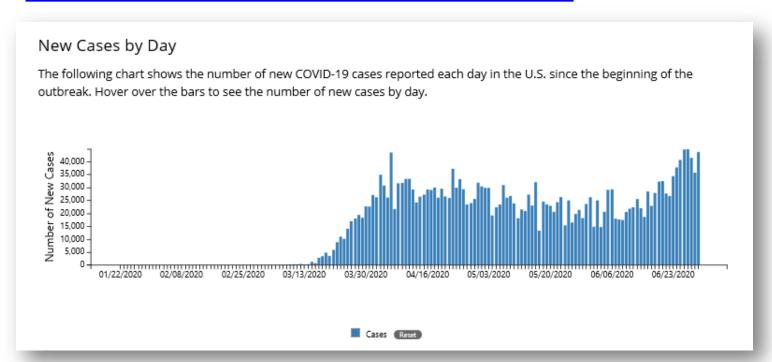


CDC COVID Data Tracker (July 1, 2020)





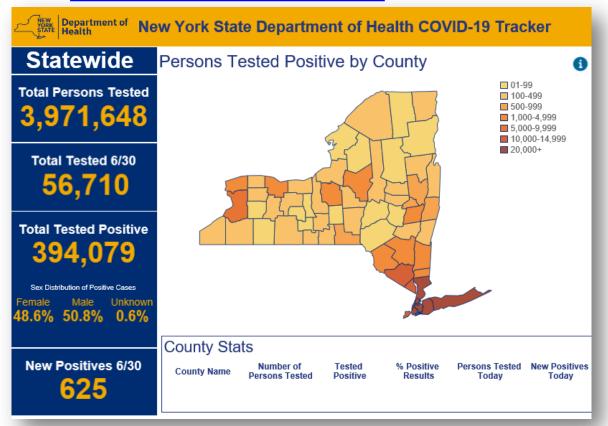
Situation Summary: Covid-19 U.S. (July 1, 2020)





NYSDOH COVID-19 Tracker (July 1, 2020)

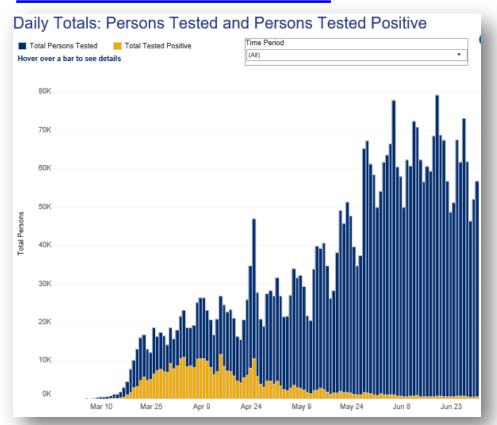
Found at: NYSDOH COVID-19 website





NYSDOH COVID-19 Tracker (July 1, 2020)

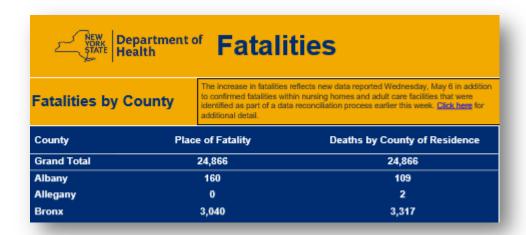
Found at: NYSDOH COVID-19 website





NYSDOH COVID-19 Tracker (July 1, 2020)

Found at: NYSDOH COVID-19 website





NYS COVID-19 Healthcare Utilization

- Continue to see decreases in hospitalization, ICU, and intubation numbers
- Currently hospitalized: 878 (decreased by 1)
 - Newly hospitalized: 96
- Current ICU: 209 (decreased by 17)
 - Current Intubation: 129 (decreased by 10)
- Fatalities (6/30): 11
- Cumulative discharges: 70,698



SARS-CoV-2 Testing for COVID-19



Updated NYS Criteria for COVID-19 Testing

- Diagnostic and/or serologic testing for COVID-19 shall be authorized by a healthcare provider when:
- An individual is symptomatic or has a history of symptoms of COVID-19 (e.g. fever, cough, and/or trouble breathing), particularly if the individual is 70 years of age or older, the individual has a compromised immune system, or the individual has an underlying health condition
- An individual is less than 21 years of age who has symptoms consistent with Multisystem Inflammatory Syndrome in Children (MIS-C)
- An individual requires a test for medical care, including being tested prior to an elective surgery or procedure, or individuals who are pregnant and their designated support person; or
- An individual has had close (i.e. within six feet) or proximate contact with a person known to be positive with COVID-19 (precautionary or mandatory quarantine)
- An individual is employed as a healthcare worker, first responder, NH employee or staff of other congregate care facility, or other essential worker who directly interacts with the public while working
- An individual is employed by an essential business and directly interacts with the public
- An individual is employed by an essential business (e.g. food production, medical supply manufacturing) or any business that has been designated to "reopen" in certain regions of the state (e.g. construction, curbside/instore pickup retail, wholesale trade); or
- An individual presents with a case where the facts and circumstances as determined by the treating clinician
 in consultation with state or local department of health officials warrant testing
- Anyone who attended a recent protest is eligible for a test
- Any New Yorker



<u>Association of Public Health Laboratories</u> Guidance on **Antigen Testing**

- June 23, 2020
- APHL Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing
- Rapid antigen tests
 - PROS
 - Relatively inexpensive
 - Short turnaround time
 - Point-of-care use (such as doctors' offices)
 - Reported high specificity
 - CONS
 - Significantly lower sensitivity than most molecular tests
- Influenza rapid antigen testing
 - Commonly produces false negative results due to low sensitivity
 - As well as false positive results when disease prevalence is low



APHL Guidance on Antigen Testing

- In settings experiencing high SARS-CoV-2 positivity rates, positive test results indicate that SARS-CoV-2 antigens were detected and that the individual is infected and presumed to be contagious
- However, false positive results can occur and are most likely in populations where the prevalence of SARS-CoV-2 infection is low
- Currently available SARS-CoV-2 antigen tests are considerably less sensitive than molecular tests and may therefore generate false negative results
- They should only be used to test symptomatic patients in populations with a high prevalence of disease
- However, false negative results can occur regardless of overall prevalence
- Presumptive negative results should be confirmed using a molecular test



APHL Guidance on Antigen Testing

- Scenarios where Ag testing may be considered:
 - Symptomatic patients with high pre-test probability (high prevalence populations)
 - Use where a rapid positive helps clinical decisions or infection control
 - However, a negative result should be confirmed with molecular test
 - Examples:
 - Outbreak situations
 - Triaging individuals with respiratory symptoms in ED or similar settings
 - In high-risk congregate settings where confirmed cases
 - Off hour testing for rapid result, followed by molecular test
 - · Remote populations with high prevalence and limited access to testing



APHL Guidance on Antigen Testing

- Scenarios where Ag testing should NOT be considered for use:
 - Screening of asymptomatic individuals
 - Testing in underserved or marginalized populations where testing may be limited
 - Alternatives to improving access of testing should be sought

Test Name	Separate Instrument Required	Authorized for Use in Waived Settings	Specimen Types	Time to Result	Test Performance*	More Information
Quidel Sofia 2 SARS Antigen FIA	Yes Sofia 2 FIA Analyzer	Yes	NP or Nasal Swabs Directly or After Transport in VTM	15-30 minutes	Sensitivity: 80% Specificity: 100%	IFU HCP



Community Mitigation and Reopening Strategies



NYS Community Mitigation and Reopening Strategy

Phase 2

 Phase 2 allows office-based workers, real estate, in-store retail shopping and some barbershop and hair salon services, outdoor dining permitted with social distancing and masks, reopening of places of worship with 25% occupancy

New York City

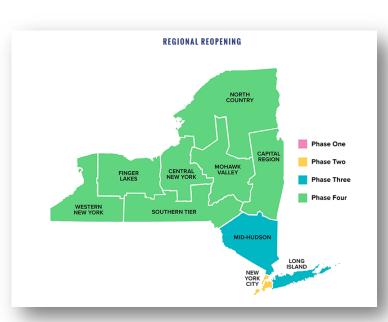
 Phase three expected Monday July 6, however, indoor dining postponed as states across the country that previously reopened indoor dining are experiencing upticks in COVID-19 cases

Phase 3

- Indoor restaurant and food services and personal care services to resume, gatherings of 25 people will be allowed, low risk youth sports can resume on July 6th (baseball/softball, gymnastics, field hockey, cross country, and crew)
- Long Island and the Mid-Hudson Region

Phase 4

- Capital region, Mohawk Valley, North Country, Central New York, Southern Tier, Finger Lakes, and Western NY
- Higher education, low-risk outdoor and indoor arts & entertainment, media production, professional sports competitions with no fans



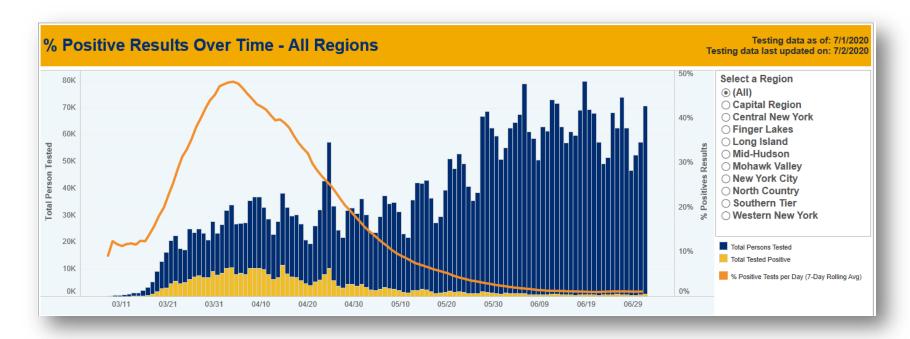


NYS Community Mitigation and Reopening Strategy

- NY Forward business reopen look up tool available <u>here</u>
- NY Forward reopening guidance available <u>here</u>
- The state's regional monitoring dashboard is available <u>here</u>

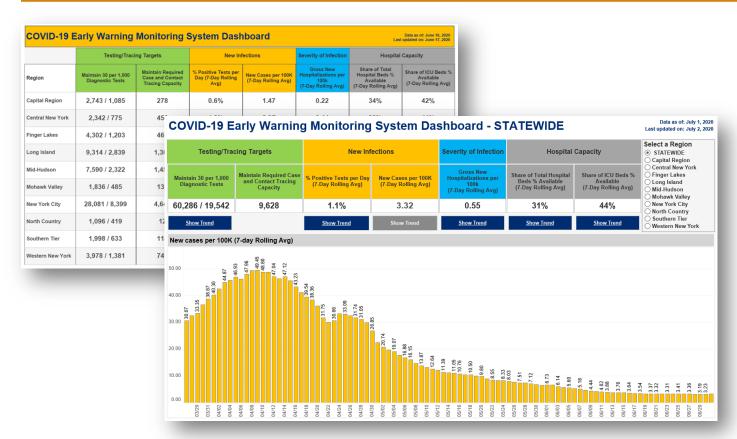


Percentage Positive Results By Region Dashboard



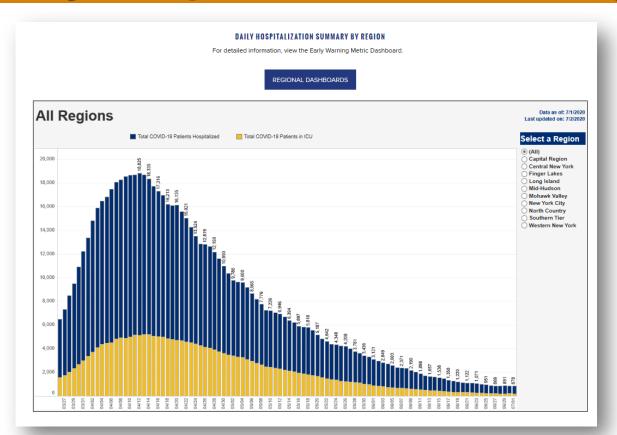


Early Warning Monitoring Dashboard





Daily Hospitalization Summary by Region



NYS Daily Hospitalization
Summary by Region



NYS Travel Advisory

- In partnership with NJ and CT, NYS has issued a travel advisory for individuals traveling from states with significant community spread of COVID-19, requiring a 14-day quarantine (issued June 25, 2020)
- NYSDOH COVID-19 Travel Advisory Website maintains a current list of states meeting the criteria for the required quarantine
- Current list:
 - Alabama, Arkansas, Arizona, California, Florida, Georgia, Iowa, Idaho, Louisiana,
 Mississippi, Nevada, North Carolina, South Carolina, Tennessee, Texas
- This is based upon a seven day rolling average, of positive tests in excess of 10%, or number of positive cases exceeding 10 per 100,000 residents
- If you have traveled from within a designated state, you must quarantine for 14 days from the last travel within the designated state, provided on the date you enter into NYS that such state met the criteria

NYS Travel Advisory - FAQs

- The requirements of the travel advisory do NOT apply to any individual passing through designated states for a limited duration (i.e., less than 24 hours) through the course of travel (stopping at rest stops for vehicles, buses, or trains or lay-overs for air travel, bus travel, or train travel)
- Exceptions for essential workers:
 - Short term (<12 hrs) and medium term (<36 hrs) essential workers
 - Essential workers should stay in their vehicle and/or limit personal exposure by avoiding public spaces as much as possible, monitor temperature and symptoms, wear a face covering when in public, social distance, clean and disinfect, avoid extended periods in public, contact with the public, and large congregate settings
 - Long-term essential workers (requiring a stay of >36 hrs, several days)
 - Seek diagnostic testing for COVID-19 as soon as possible upon arrival (within 24 hours) to ensure they are not positive
 - · Other measures as above
 - For reference, an "essential worker" is:
 - Any individual employed by an entity included on the Empire State Development (ESD) Essential Business list; or
 - Any individual who meets the COVID-19 testing criteria given status as employed as a health care
 worker, first responder, or in any position within a nursing home, long-term care facility, or other
 congregate care setting, or an individual who is employed as an essential employee who directly
 interacts with the public while working, pursuant to DOH Protocol for COVID-19 Testing, issued May
 31, 2020, or
 - Any other worker deemed such by the Commissioner of Health
- NYSDOH COVID-19 Travel Advisory Guidance



Therapeutic Updates



Therapeutic Updates

Dexamethasone

- Preliminary, unpublished, analysis of data from the Randomized Evaluation of COVID-19
 Therapy (RECOVERY) study in the U.K.
 - Among 6,425 hospitalized patients, 2,104 in the dexamethasone arm and 4,321 in the control arm, primary outcome 28-day mortality
 - Among those on mechanical ventilation, 29% in dexamethasone arm died compared to 40.7% in control arm (RR 0.65; 95% CI, 0.51–0.82, P < 0.001)
 - Among those on supplemental oxygen, 21.5% in the dexamethasone arm died compared to 25% in the control arm (RR 0.80; 95% CI, 0.70–0.92, P = 0.002)
 - No benefit observed in those who did not require oxygen at enrollment

NIH COVID-19 Treatment Guidelines - Dexamethasone

- Updated June 25, 2020
- Recommends using dexamethasone (at a dose of 6 mg per day for up to 10 days) in patients with COVID-19 who are mechanically ventilated and in patients with COVID-19 who require supplemental oxygen
- The Panel recommends against using dexamethasone in patients with COVID-19 who do not require supplemental oxygen

 Department

Multisystem Inflammatory
Syndrome Associated with
COVID-19 in Children (MIS-C)



MIS-C

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Multisystem Inflammatory Syndrome in U.S. Children and Adolescents

L.R. Feldstein, E.B. Rose, S.M. Horwitz, J.P. Collins, M.M. Newhams, M.B.F. Son, J.W. Newburger, L.C. Kleinman, S.M. Heidemann, A.A. Martin, A.R. Singh, S. Li, K.M. Tarquinio, P. Jaggi, M.E. Oster, S.P. Zackai, J. Gillen, A.J. Ratner, R.F. Walsh, J.C. Fitzgerald, M.A. Keenaghan, H. Alharash, S. Doymaz, K.N. Clouser, J.S. Giuliano, Jr., A. Gupta, R.M. Parker, A.B. Maddux, V. Havalad, S. Ramsingh, H. Bukulmez, T.T. Bradford, L.S. Smith, M.W. Tenforde, C.L. Carroll, B.J. Riggs, S.J. Gertz, A. Daube, A. Lansell, A. Coronado Munoz, C.V. Hobbs, K.L. Marohn, N.B. Halasa, M.M. Patel, and A.G. Randolph, for the Overcoming COVID-19 Investigators and the CDC COVID-19 Response Team*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Multisystem Inflammatory Syndrome in Children in New York State

Elizabeth M. Dufort, M.D., Emilia H. Koumans, M.D., M.P.H.,
Eric J. Chow, M.D., M.P.H., Elizabeth M. Rosenthal, M.P.H.,
Alison Muse, M.P.H., Jemma Rowlands, M.P.H., Meredith A. Barranco, M.P.H.,
Angela M. Maxted, D.V.M., Ph.D., Eli S. Rosenberg, Ph.D., Delia Easton, Ph.D.,
Tomoko Udo, Ph.D., Jessica Kumar, D.O., Wendy Pulver, M.S., Lou Smith, M.D.,
Brad Hutton, M.P.H., Debra Blog, M.D., M.P.H., and Howard Zucker, M.D.,
for the New York State and Centers for Disease Control and Prevention
Multisystem Inflammatory Syndrome in Children Investigation Team*

- Further evidence of temporal, geographic, laboratory/exposure linkage of COVID-19 with MIS-C
- MIS-C presented differently than children with Kawasaki disease; generally were older with more severe clinical course, more hypotension/shock and severe cardiac disease

MIS-C

- Further evidence of that most children with this syndrome had no significant underlying medical conditions
- Health disparities we have seen in other aspects of the COVID-19 pandemic are being seen with syndrome as well
- We found variations in clinical manifestations according to age
 - The prevalence of dermatologic symptoms was highest among children 0 to 5 years of age, and the prevalence of myocarditis was highest among the adolescents
 - Meanwhile, gastrointestinal symptoms were high in all age groups
- Elevated levels of C-reactive protein (CRP), d-dimer, and troponin were found in 100%, 91%, and 71% of the patients tested, respectively



Approach to MIS-C Guidance

COVID-19 associated Multisystem Inflammatory Syndrome in Children (MIS-C guidelines: a Western New York approach

Evaluation for COVID 19 Associated Multisystem Inflammatory Syndrome in Children (MIS-C)

Consider this condition in children presenting with fevers without an explanatory alternative diagnosis and any of the following: after initial resolution of known/highly suspected COVID-19 infection or recent COVID-19 exposure, symptoms of Kawasaki Disease (rash, conjunctivitis, oral/mucosal inflammation), or systemic illness with signs of shock or significant vomiting/diarrhea/abdominal pain. *see below CDC case definition

Overlap with MIS-C definition, but mild illness, mild lab abnormalities on screening labs, and lacking alternative diagnosis



Perform Set 1 studies not already performed Additional studies to consider

- chest x-ray
- abdominal imaging as indicated



If concerning labs or clinical decline perform Set 2

Sick child / cardiogenic shock / overlap with Kawasaki disease (KD) / toxic-shock like - Admit and....



- Establish good IV access and start fluids: judicious use with frequent reevaluation
- · Perform Set 1 and 2 studies if not already done
- · Notify local Department of Health
- Consults:
 - PICU (all patients)
 - · Infectious Diseases (all patients)
- · Consider: Hematology, Rheumatology
- Urgent Echo and Cardiology consult for any of the following:
 - · Hemodynamically compromised (hypotension, tachycardia out of proportion of fever)
 - Troponin or BNP elevated
 - · EKG suggestive of myocardial injury/inflammation
 - · If considering KD and on day 9 or longer of fevers
- Empiric Antibiotics (will vary, guided by ID) consider:
 - Ceftriaxone + Metronidazole for abdominal concern
 - Vancomycin, Clindamycin, Cefepime for Toxic Shock

Set 1- Studies

COVID-19 PCR (if not performed within 48 hours) COVID IgG (unless known +) Respiratory viral panel EKG

Procalcitonin

Urinalysis with microscopic

(clean catch to assess urethritis)

Blood culture

- Urine culture
- A CBC with differential
- A CMP (albumin and LFTs) A CRP
- A Ferritin
- A D-dimer
- A Troponin ABNP
- A LDH VBG
- ^B Lactate B PT/PTT
- ^B Fibrinogen ^BCK
- ^B LDH

Set 2- Studies

Contents lists available at ScienceDirect



Progress in Pediatric Cardiology



journal homepage: www.elsevier.com/locate/ppedcard

Evaluation for COVID 19 Associated Multisystem Inflammatory Syndrome in Children (MIS-C)

Editorial

COVID-19 associated Multisystem Inflammatory Syndrome in Children (MIS-C) guidelines; a Western New York approach

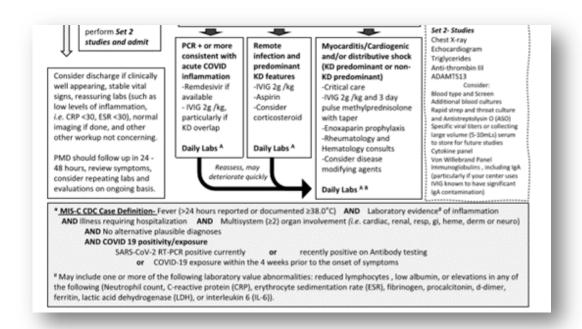
Consider this condition in children presenting with fevers without an explanatory alternative diagnosis and any of the following: after initial resolution of known/highly suspected COVID-19 infection or recent COVID-19 exposure, symptoms of Kawasaki Disease (rash, conjunctivitis, oral/mucosal inflammation), or systemic illness with signs of shock or significant vomiting/diarrhea/abdominal pain. *see below CDC case definition Set 1- Studies COVID-19 PCR (if not Overlap with MIS-C Sick child / cardiogenic shock / overlap with performed within 48 hours) Kawasaki disease (KD) / toxic-shock like definition, but mild COVID IgG (unless known +) Respiratory viral panel illness, mild lab Admit and.... abnormalities on Procalcitonin screening labs, and Urinalysis with microscopic Establish good IV access and start fluids: judicious use with (clean catch to assess lacking alternative frequent reevaluation unethritis) diagnosis Perform Set 1 and 2 studies if not already done Blood culture Notify local Department of Health Urina cultura Consults *CBC with differential *CMP (albumin and LFTs) PICU (all patients) · Infectious Diseases (all patients) Perform Set 1 studies not *Ferritin · Consider: Hematology, Rheumatology already performed A D-dimer Additional studies to consider Urgent Echo and Cardiology consult for any of the following: *Troponin · Hemodynamically compromised (hypotension, - chest x-ray tachycardia out of proportion of fever) abdominal imaging as *LDH · Troponin or BNP elevated indicated *VBG · EKG suggestive of myocardial injury/inflammation * Lactate * PT/PTT . If considering KD and on day 9 or longer of fevers * Fibrinogen Empiric Antibiotics (will vary, guided by ID) consider: · Ceftriaxone + Metronidazole for abdominal concern If concerning labs *LDH · Vancomycin, Clindamycin, Cefepime for Toxic Shock or clinical decline perform Set 2 Set 2- Studies Chest X-ray studies and admit PCR + or more Myocarditis/Cardiogenic Remote Echocardiogram consistent with infection and and/or distributive shock Triglycerides acute COVID predominant (KD predominant or non-Anti-thrombin III Consider discharge if clinically inflammation KD features KD predominant) ADAMTS13 well appearing, stable vital -Remdesivir if -IVIG 2g /kg Consider -Critical care Blood type and Screen signs, reassuring labs (such as available -Aspirin -IVIG 2g /kg and 3 day Additional blood cultures low levels of inflammation. - IVIG 2g /kg, -Consider pulse methylprednisolone Rapid strep and throat culture i.e. CRP <30, ESR <30), normal particularly if corticosteroid with taper and Antistreptolysin O (ASO) imaging if done, and other KD overlap Specific viral titers or collecting Enoxaparin prophylaxis large volume (5-30mLs) serum other workup not concerning -Rheumatology and to store for future studies Daily Labs A Daily Labs A Hematology consults Cytokine panel PMD should follow up in 24 --Consider disease Von Willebrand Panel 48 hours, review symptoms, Reassess, may modifying agents mmunoglobulins . Including IgA (particularly if your center us consider repeating labs and IVIG known to have significant evaluations on ongoing basis. * MIS-C CDC Case Definition- Fever (>24 hours reported or documented ≥38.0°C) AND Laboratory evidence* of inflammation AND Illness requiring hospitalization AND Multisystem (≥2) organ involvement (i.e. cardiac, renal, resp. gi, heme, derm or neuro) AND No alternative plausible diagnoses AND COVID 19 positivity/exposure SARS-CoV-2 RT-PCR positive currently or recently positive on Antibody testing or COVID-19 exposure within the 4 weeks prior to the onset of symptoms

May include one or more of the following laboratory value abnormalities: reduced lymphocytes, low albumin, or elevations in any of

the following (Neutrophil count, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer,

ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6)).

Approach to MIS-C Guidance





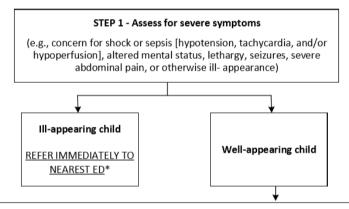
MIS-C Guidance for Ambulatory Care Providers

NYC DOHMH MIS-C Guidance for Ambulatory Care Providers

- Refer ill-appearing children with a possible MIS-C case to the emergency department (ED) of the children's hospital where they typically obtain care, or to the closest ED where care by pediatric subspecialists is available, when possible.
 - For MIS-C, a multidisciplinary approach to evaluation and treatment that involves pediatric subspecialists is critical, as is access to clinical and diagnostic laboratory testing with rapid turnaround time for results. Cases can progress rapidly to shock.
- For well-appearing children with an illness potentially compatible with MIS-C who do not meet criteria for ED referral initially, close follow-up is recommended.
 - Laboratory testing may be considered, but is not essential for the evaluation of MIS-C in the ambulatory care setting for an otherwise well-appearing child. If laboratory testing is conducted, increasing inflammatory markers (e.g., C-reactive protein) can be indicative of disease progression.

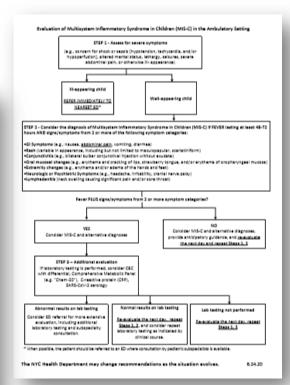
NYC DOHMH MIS-C Guidance for Ambulatory Care Providers

Evaluation of Multisystem Inflammatory Syndrome in Children (MIS-C) in the Ambulatory Setting



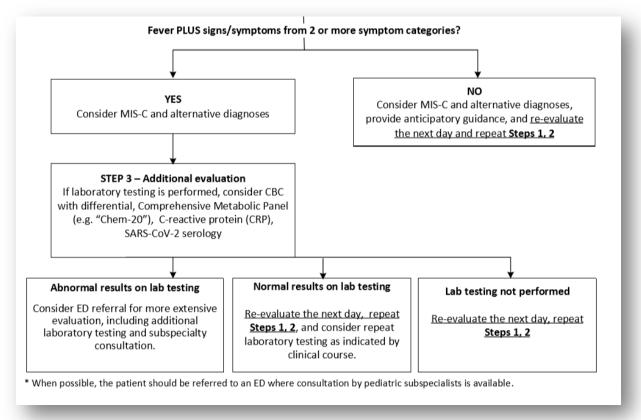
STEP 2 - Consider the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) if FEVER lasting at least 48-72 hours AND signs/symptoms from 2 or more of the following symptom categories:

- •GI Symptoms (e.g., nausea, abdominal pain, vomiting, diarrhea)
- Rash (variable in appearance, including but not limited to maculopapular, scarlatiniform)
- •Conjunctivitis (e.g., bilateral bulbar conjunctival injection without exudate)
- •Oral mucosal changes (e.g., erythema and cracking of lips, strawberry tongue, and/or erythema of oropharyngeal mucosa)
- •Extremity changes (e.g., erythema and/or edema of the hands and feet)
- •Neurologic or Psychiatric Symptoms (e.g., headache, irritability, cranial nerve palsy)
- •Lymphadenitis (neck swelling causing significant pain and/or sore throat)





NYC DOHMH MIS-C Guidance for Ambulatory Care Providers





MIS-C Associated with COVID-19

New York State Department of Health

HELP



The Spectrum of Multisystem
Inflammatory Syndrome in Children
(MIS-C)
June 11, 2020



Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus 2019 (COVID-19) May 21, 2020

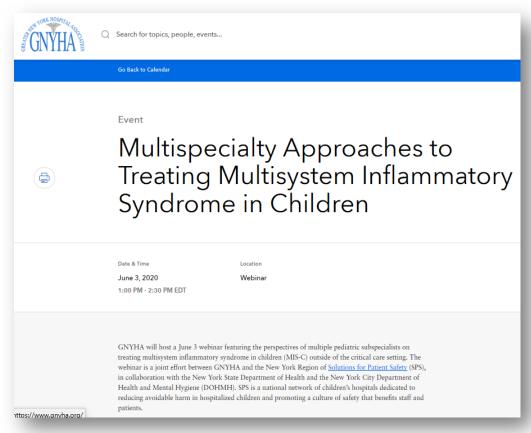


COVID-Related Pediatric Multi-System Inflammatory Syndrome May 14, 2020



Webcast link: https://totalwebcasting.com/view/?id=nysdohcovid

MIS-C Associated with COVID-19





MIS-C Associated with COVID-19

NIH COVID-19 Treatment Guidelines

- Limited information available on treatment for MIS-C
- Supportive care remains the mainstay of therapy
- Currently insufficient data to recommend either for or against any therapeutic strategy for the management of MIS-C
- Although no definitive data are available, many centers consider the use of intravenous immune globulin, steroids, and other immunomodulators (including interleukin-1 and interleukin-6 inhibitors) for therapy, and antiplatelet and anticoagulant therapy
- The role of antiviral medications is not clear at this time
- MIS-C management decisions should involve a multidisciplinary team of pediatric specialists in intensive care, infectious diseases, cardiology, hematology, and rheumatology

Elizabeth Rausch-Phung, MD, MPH Director, Bureau of Immunization NYSDOH



Routine and Catch-Up Vaccination During COVID-19



Routine Vaccination of Children, Adolescents and Adults

- Routine vaccination of children, adolescents and adults (including pregnant women) should <u>not</u> be delayed due to COVID-19
- Critical to prevent outbreaks of vaccine-preventable diseases, protect vulnerable patients, the healthcare system and infrastructure
- Use every available opportunity this fall and winter to offer influenza vaccine to all eligible persons age 6 months and older

Separate Well Patients From Sick Patients

- Schedule well visits in the morning and sick visits in the afternoon
- Separate areas for sick visits and well visits
- Close waiting rooms: have patients wait in cars and call or text them when their exam room is ready
- Screen patients and caregivers for symptoms of COVID-19 prior to entering the facility
- Only allow 1 caregiver per child present at a time

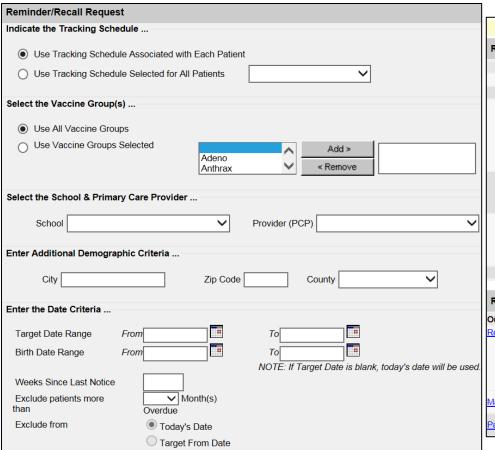


Infection Control Strategies

- Wear medically-appropriate face masks
- Wear eye protection while administering vaccines in areas with moderate or substantial community transmission
- Wear gloves while administering nasal or oral vaccines
- Implement temperature and symptom checks for all staff at the beginning of each shift and every 12 hours while on duty
- Follow CDC and OSHA guidance for cleaning exam rooms



Reminder/Recall



org	anization	Lori's Pediatrics	• user	Lori Isa	bella-Rhoade	es • role	Admin User (Pro	vider)	
Reminder	Request	Process Summa	ry						
Step			Criter	ia Evalua	ted at this Ste	р		Patie	nts
1	Patients a	ssociated with <i>Lori</i> '	s Pediatr	ics.				56	
2	Patients in	mmunized by Lori's	Pediatric	S.				34	
3	, also in a manage of the contained						28		
4	Additional • City is	hat have a Valid Add criteria includes: not specified ode is not specified.	dress.					8	
5	Patients that meet the following criteria regarding vaccination status: Patients that are Recommended or Overdue for one or more vaccinations as of 06/27/2018; Use all vaccine groups; Use tracking schedule associated with each patient. Exclude Overdue Reminders is not specified.								
				7	otal Number o	of Patients	Eligible for Remine	der 8	
Reminder	Request	Output Options							
Output		Description				Add	ditional Input		
Reminder L	<u>etter</u>	Standard Remind	er Letter.		Report Name				
					Free Text	Cheers,		^	
						Dr. Rhoade	es ————————————————————————————————————		
					Phone #				
Mailing Lab	els	Avery Mailing Lab	els.		Report Name				
Patient Que	ry Listing	A list of patients b criteria.	ased on t	the report	Report Name				

Reminder/Recall Output

Dear Sharon F Forbes,

Our records indicate that Sharon F Forbes has received the following immunizations:

Immunizations History			
Immunization	Date Administered	Series	
MMR	04/23/2005	1 of 2	
Varicella	01/01/1959	1 of 2	

Our records also show that Sharon may be due for the following immunizations. If Sharon received these or other immunizations from another health care provider, please call our office so that we can update Sharon's record. Otherwise please take Sharon to a health care provider to receive them.

Vaccines Recommended by Selected Tracking Schedule			
Vaccine	Date Needed		
Flu, unspecified formulation	08/01/2017		
MMR	05/21/2005		
TdaP > 7 years	01/01/1965		
Varicella	05/21/2005		
Zoster Subunit	01/01/2008		

Cheers,

Dr. Rhoades



Reminder/Recall Output

SHARON F FORBES 499 WALTON DRIVE

CHEEKTOWAGA NY 14225

To the Parent/Guardian of: LOIS ANNE ISAACS 855 DRAKE

MARION NY 11213

To the Parent/Guardian of:

SAMANTHA JONES 16 FAST 4TH ST APT 1

MOUNT VERNON NY 10550

To the Parent/Guardian of: JOHN B NYSIISTESTB 100 MAIN STREET BUFFALO NY 14201

To the Parent/Guardian of:

FRI SMITH

123 MAIND ST

DESMOND NY 96813

Patient Name (FM	1L)	Phone Number	Address	City/State/Zip
LYNETTE PATTY BRA	NDEIS - 05/15/200	5	300 VILAS	ATHENS, NY 11040
Vaccine	Recmd Day	Immunization Dat	tes	
HepB	05/15/2005			
HPV	11/15/2014	1) 05/15/2014 (PD)	2) 05/15/2014	
Influenza	08/01/2017			
Mening	05/15/2016			
MMR	05/15/2006			
Polio	07/15/2005			
Td/Tdap	05/15/2012			
Varicella	05/15/2018			

SHARON F FORBES - 01/01/1958		499 WALTON DRIVE	CHEEKTOWAGA, NY 14225
Vaccine	Recmd Day	Immunization Dates	
Influenza	08/01/2017		
MMR	05/21/2005	1) 04/23/2005	
Td/Tdap	01/01/1965		
Varicella	05/21/2005	1) 01/01/1959	
Zoster	01/01/2008		

OIS ANNE ISAACS - 09/26/2004		855 DRAKE	MARION, NY 11213	
Vaccine	Recmd Day	Immunization Dates		
DTP/aP	Max Age Exceede	ed		
НерВ	01/02/2018	1) 11/05/2013 (NV) 2) 06/25/2015 (NV) 3) 12/05/2017		
Hib	Max Age Exceede	ed 1) 12/05/2017 (NV)		
HPV	09/26/2015			
Influenza	08/01/2018	1) 11/05/2013 2) 11/08/2013 (NV) 3) 02/01/2018		
Mening	09/26/2015			
MMR	Complete	1) 09/26/2005 2) 01/01/2018		
Polio	12/25/2015	1) 11/05/2013 2) 06/25/2015		
Td/Tdap	12/25/2015	1) 11/05/2013 2) 06/25/2015		
Varicella	01/29/2018	1) 11/08/2013		

Vaccine Supplies

- Assess patients due or overdue for vaccines
- Plan for increased vaccine needs as patients catch up on missing doses
- Order enough vaccine for a 2-3 month supply
- If ordering more VFC vaccine than usual
 - Call the NYS VFC program at 1-800-543-7468, and
 - Make a note in the comments section of your order explaining the need for additional vaccine



Simultaneous Administration

- The CDC, AAP and AAFP all recommend simultaneous administration of all vaccines for which a patient is eligible at the time of a visit
- Safe, effective, maximizes protection and minimizes missed opportunities to vaccinate
- Combination vaccines can reduce the numbers of shots needed, improve immunization coverage and reduce healthcare costs



Minimize Barriers to Access

- By-appointment vaccine-only clinics for patients who only need vaccines or to complement telemedicine well child visits
- Weekend and extended hours clinics improve convenience and accessibility for parents



Report to NYSIIS or the CIR

- All vaccines given to children less than 19 years of age must be reported to NYSIIS (outside of NYC) or the Citywide Immunization Registry (inside NYC)
- Vaccines administered to adults may be voluntarily reported to NYSIIS or the CIR, with the patient's consent
- NYSIIS and the CIR are comprehensive lifetime vaccine records that may be accessed by any NYS healthcare provider treating your patient now or in the future
- Critical for continuity of care



Standards for Adult Immunization Practice

Assess immunization status at every clinical encounter

Strongly recommend needed vaccinations

Administer needed vaccinations or Refer

Document vaccines received by your patients



Contact Information

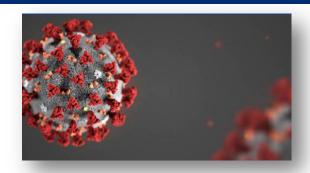
- NYSDOH Bureau of Immunization (518) 473-4437 or immunize@health.ny.gov
- NYSIIS Help Desk 1-866-389-0371 or nysiis@health.ny.gov



Marcus Friedrich, MD, MHCM, MBA, FACP Chief Medical Officer, Office of Quality and Patient Safety NYSDOH



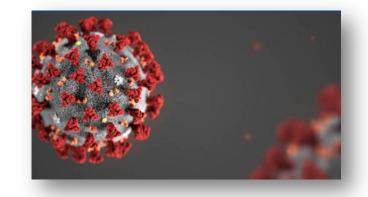
COVID-19 Healthcare Capacity and Response



- Travel Advisory in Healthcare
- Encouraging Access to Healthcare







Quick Tips for Clinician Wellbeing in The Era of COVID-19

July 2, 2020

Louis S. Snitkoff, MD, FACP Immediate Past-President American College of Physicians, NY Chapter

Healthcare Provider Wellness Webinar Next Week

Supporting Well-Being in COVID and Beyond

Thursday July 9th 1-2PM

Call in: 844-512-2950

Access code: 2395356



Healthcare Provider/Physician Wellness

- The state is partnering with the Kate Spade New York Foundation and Crisis Text Line to provide a 24/7 emotional support service for frontline healthcare workers
- Text NYFRONTLINE to 741-741 to access these emotional support services
- New York State-regulated health insurers will be required to waive costsharing, including deductibles, copayments and coinsurance, for innetwork mental health services for frontline essential workers during COVID-19



Mental Health Resources

NYS Mental Health Helpline 1-844-863-9314

 The helpline is staffed by specially trained volunteers, including mental health professionals, who have received training in crisis counseling related to mental health consequences of infectious disease outbreaks, typical stress reactions, anxiety management, coping skills, and telephonic counseling



Healthcare Provider Well-being Resources

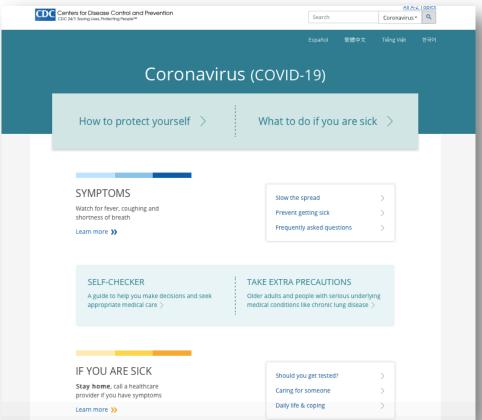
MSSNY	<u>AAFP</u>
<u>ACP</u>	AAP
NAM	AHRQ well-being AHRQ burnout
<u>AMA</u>	<u>NIH</u>
<u>IHI</u>	<u>Stanford</u>



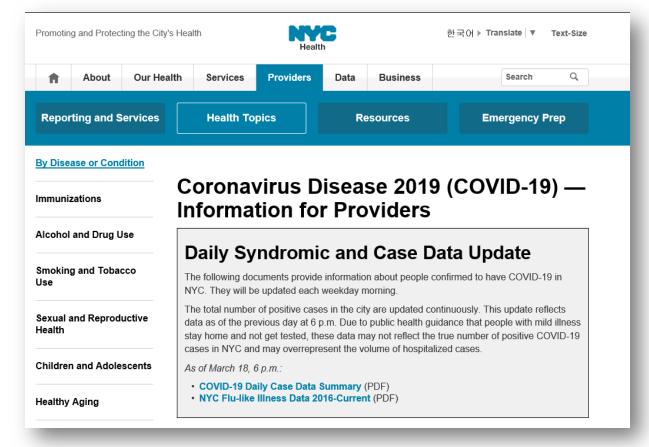
COVID-19 Resources



CDC COVID Website

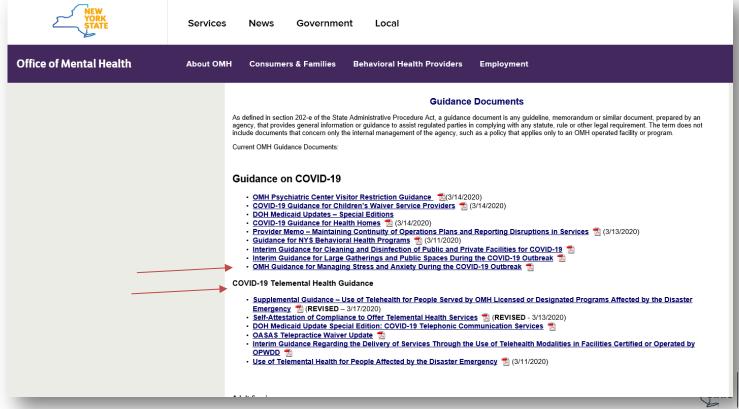


NYC DOHMH COVD-19 Webpage





Mental Health Resources



Department Education of Health Department

- For everyone
- For individuals receiving mental health services
- For parents
- For caregivers of older adults
- For mental health providers

March 16, 2020



Feeling Stressed About Coronavirus (COVID-19)?

Managing Anxiety in an Anxiety-Provoking Situation

The outbreak of COVID-19 around the world has led to the spread of fear and panic for individuals and communities. In addition to following physical precautions guidelines, individuals should be taking care of their psychological well-being.

This guide includes tips for the following populations:

- For Everyone
- · For Individuals Receiving Mental Health Services
- For Parents, Including Parents of Children with Pre-Existing Anxiety Disorders
- · For Caregivers of Older Adults
- · For Mental Health Providers

For Everyone:

• Reduce anxiety by reducing risk. Ways to reduce risk include practicing good hygiene (e.g.



NYS Medicaid Telehealth Updates and Guidance

NYSDOH COVID-19 Guidance for Medicaid Providers website

- Webinar: New York State Medicaid Guidance Regarding Telehealth, Including Telephonic, Services During the COVID-19 Emergency - 5.5.2020
 - Slides (PDF)
 - Recording Coming Soon
- Frequently Asked Questions (FAQs) on Medicaid Telehealth Guidance during the Coronavirus Disease 2019 (COVID-19) State of Emergency - (Web) -(PDF) - Updated 5.1.2020



Telehealth Guidance

American College of Physicians Telehealth Resource:

www.acponline.org/practice-resources/business-resources/health-information-technology/telehealth

CDC Outpatient and Ambulatory Care Setting Guidance:

www.cdc.gov/coronavirus/2019-ncov/hcp/ambulatory-care-settings.html

Medicaid:

www.health.ny.gov/health_care/medicaid/program/update/2020/



COVID-19 Weekly Healthcare Provider Update Compilation: As of June 17, 2020, 9:00 AM

The information in this compilation is current only as of the above date and time.

Purpose: The purpose of this weekly publication is to provide healthcare providers in New York State with a consolidated update of guidance released by the New York State Department of Health (NYSDOH) related to the COVID-19 pandemic response. This will show only current guidance for any given topic and will be updated to reflect new guidance.

As a reminder, all advisories and informational messages (including webinar invitations) are distributed through the Integrated Health Alerting Network System (IHANS), an application housed on the <u>Health Commerce</u> <u>System (HCS)</u>. If you are not receiving IHANS notifications, please work with your site's HCS coordinator. Additional COVID-19 resources may be found on the NYSDOH webpage under <u>Information for Healthcare</u> <u>Providers</u>.

Recordings of COVID-19 Weekly Healthcare Provider Updates are also available on the NYSDOH webpage.

Guidance/Health Advisory Topic	Link(s)	Date
Testing/ Specimen	Additional Capacity Guidance (Collection, triage, treatment)	3/19/20
Collection	Specimen Collection and Handling to Allow NP and Saliva Specimen	4/01/20
	Wadsworth Specimen Collection, Handling and Transport	4/01/20
	Updated Infectious Disease Requisition Form	4/09/20
	Updated Infectious Disease Requisition Guidance	4/09/20
	Private Practice Collection Guidance	4/19/20
	The NYSDOH Wadsworth Center's Assay for SARS-CoV-2 IgG FAQ	4/20/20
	Serology Testing	4/30/20
	Specimen Collection Training for Unlicensed Individuals	5/15/20
	Authorization of Licensed Pharmacists to Order COVID-19 Tests	5/15/20
	SARS-CoV-2 Diagnostic Testing FAQ	5/15/20
	COVID-19 Testing Next Steps	5/12/20
	Protocol for COVID-19 Testing Applicable to All Health Care Providers and LHDs	5/31/20
Infection Control	Requests for PPE should go through your county OEM	3/23/20
and PPE	PPE Shortage Guidance	4/02/20
	Optimizing PPE (CDC)	4/22/20
	Infection Control Guidance (CDC)	4/24/20
Quarantine/ Isolation	Guidance for <u>Local Health Departments</u> highlighting definitions and situations for quarantine and isolation.	4/07/20
	Precautionary Quarantine, Mandatory Quarantine, and Isolation	4/16/20
	Discontinuation of Isolation for Patients with COVID-19 who are Hospitalized, in Nursing Homes, or in Other Congregate Settings	4/19/20
	In registre fromes, or in our conditude settings	

HCP Compilation (Week of June 17th)

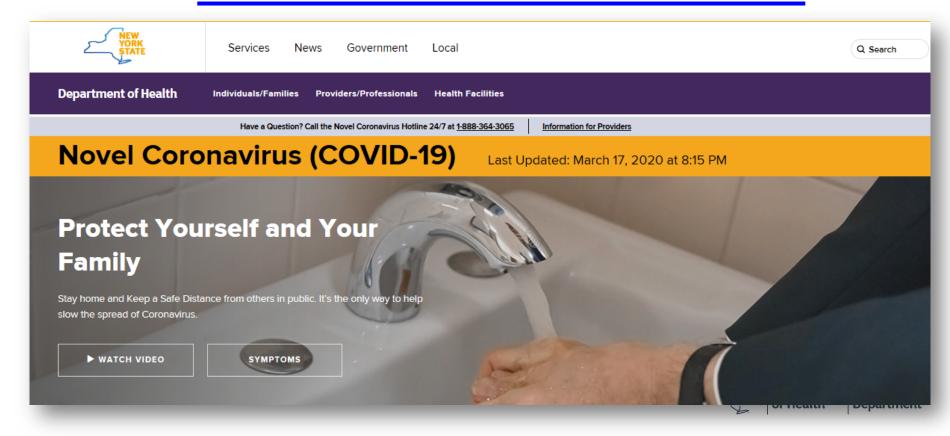
For questions, contact covidproviderinfo@health.ny.gov

NYSDOH COVID-19 Weekly HCP Update Compilation



July 16, 2020 73

NYSDOH COVID-19 Website



PROTECTING THE PUBLIC HEALTH OF ALL NEW YORKERS

Mandatory and Precautionary Quarantine	Mass Gatherings	Healthcare Providers	Nursing Homes
Schools	Childcare Providers	Employees & Employers	Insurance
Voting	International Travel	Cyber Security	Price Gouging



Symptoms

The 2019 novel coronavirus may cause mild to severe respiratory symptoms.

▶ WHAT TO LOOK FOR



COVID-19 Testing

Learn more about testing protocol now that the FDA has approved New York to begin its own testing.

OVERVIEW	•
MOBILE TESTING	-
PROTOCOL FOR TESTING	•
LEARN MORE	



Know Your Rights

The health and safety of New Yorkers is the top priority, co-pays for telehealth visits have been waived.

TESTING	•
INSURANCE	•
UNEMPLOYMENT	•
LEARN MORE	

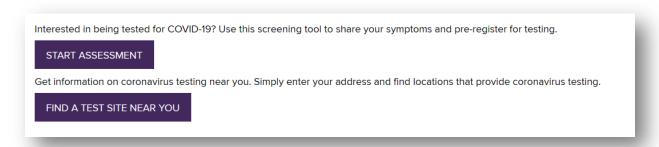


NYS Specimen Collection Sites - COVID-19 Testing

- NYSDOH Find Test Site Near You Website
 - NYS specimen collection sites, healthcare settings, pharmacies, and other
 - More than 800 specimen collection or testing sites have been identified
- For the NYS specimen collection sites:
 - Call the New York State COVID-19 Hotline at 1-888-364-3065

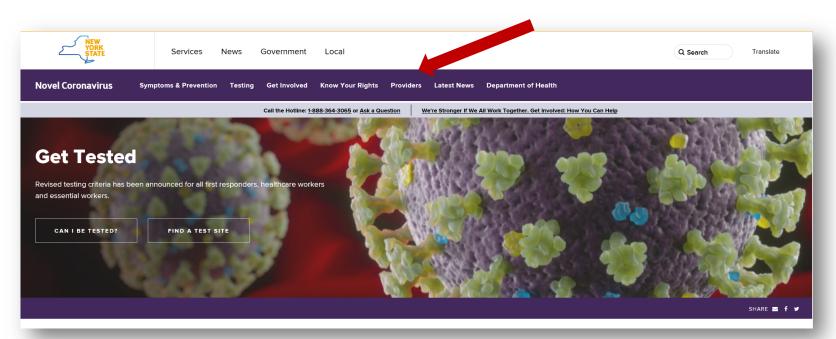
OR

 Visit the NYSDOH website <u>www.covid19screening.health.ny.gov</u> to be screened for eligibility, and if eligible, have an appointment set up at one of the State's testing sites





NYSDOH COVID-19 Website





Resources



Mirror Clings



To order mirror clings for public use email the NYSDOH:

bmcc@health.ny.gov







Mirror Clings

To order mirror clings for public use email the NYSDOH:

bmcc@health.ny.gov



Face Masks and Coverings for COVID-19





- You must wear a face mask or face covering in public when social distancing (staying at least 6 feet apart) is not possible, unless a face covering is not medically tolerated. This includes on public transport, in stores and on crowded sidewalks.
- Children over 2 years of age should wear a face mask in public, too. Children under 2 years of age should NOT wear face coverings for safety reasons.
- Cloth face coverings should be made from fabric you can't see through when held up to the light. They must be cleaned before reusing.
- · Disposable paper face masks should be used for one outing outside the home. They cannot be properly cleaned.
- The best way to prevent COVID-19 is to continue social distancing (staying at least 6 feet away from others), even when
 wearing a face covering.

Putting On Face Covering

- DO clean your hands with soap and water or if that's not available, alcohol-based hand sanitizer, before putting on your face covering.
- Make sure the face covering covers both your nose and mouth.
- DON'T wear your mask hanging under your nose or mouth or around your neck. You won't get the protection you need.
- DON'T wear the face covering on top of your head, or take it off and on repeatedly. Once it is in place, leave the covering in place until you are no longer in public.

13105

Taking Off Face Covering

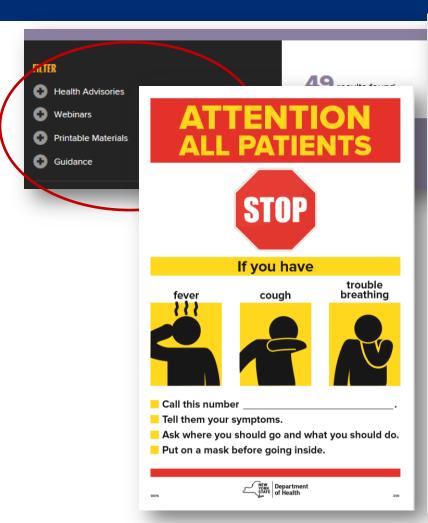
- DO clean your hands with soap and water or if that's not available, alcohol-based hand sanitizer, before taking off your face covering.
- · Remove your mask only touching the straps.
- Discard the face covering if it is disposable. If you are reusing (cloth), place it in a paper bag or plastic bag for later.
- · Wash your hands again.
- When cleaning a cloth face covering, DO put in the washer (preferably on the hot water setting).
- Dry in dryer at high heat. When it is clean and dry, place in a clean paper or plastic bag for later use. If you live in a household with many people, you might want to label the bags with names so the face coverings are not mixed up.



Department of Health

5/20





ATTENTION ALL VISITORS



NO VISITORS ARE ALLOWED AT THIS TIME

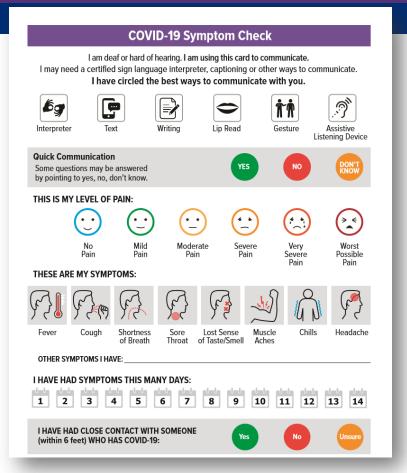
If you feel there is an urgent need for visitation, please contact ______.

DO NOT VISIT





Department of Health



https://coronavirus.health.ny.gov/system/files/documents/2020/05/13 104 015773 covid19 hearingimpairedcard version5.pdf



Department of Health

COVID-19 Testing Next Steps

You are being tested for a virus that causes COVID-19. If you have symptoms of the disease, or if you have been in contact with someone who is infected, you will be asked to stay apart from others. This is also called isolation or quarantine. COVID-19 spreads easily. Staying apart helps stop the disease from spreading.

Symptoms Include:

Fever, cough, difficulty breathing









Other symptoms may include: Chills, muscle aches, headache, sore throat, abdominal pain, vomiting, diarrhea, runny nose, fatigue, wheezing, or new loss of taste or smell.

You Should Be Isolated If:

 You have symptoms and think you may have been infected with the virus.

You Should Be Quarantined If:

 You have been in close contact with someone known to have COVID-19, even if you don't have symptoms. Close contact means sharing the same household, direct physical contact, or being within six feet for more than 10 minutes.

See back for more information.

If You are an Essential Worker:

You can **ONLY** return to work while you wait for your test results if:

- You have your employer's permission to
 do so
- · You DO NOT have symptoms.
- And you have NOT had contact with a person known to have COVID-19.

In addition, you must continue to:

- Practice social distancing (stay more than 6 feet from others).
- Use appropriate personal protective equipment (PPE).
- Wear a mask when less than 6 feet away from others in public.
- Take your temperature and monitor your symptoms daily.



www.coronavirus.health.ny.gov

Over ---

5/20

How to Isolate or Quarantine:



Stay home, except to visit a doctor.



If you must see a doctor, call ahead and avoid using public transport such as subways, buses, taxis.



Don't have visitors.



Separate yourself in a room that is not shared with others. Stay at least 6 feet away from others at all times.



Use a separate bathroom, if possible, and disinfect after each use.



Arrange for food, medicine, and other supplies to be left at your door.



Cover your coughs and sneezes. Throw away used tissues. Bag your trash and leave outside your door.



Don't touch pets.



Arrange for others to care for your children, if possible.



Wear a face mask if you must be around others.



Wash your hands often with soap and water for 20 seconds each time, or if unavailable, use hand sanitizer with at least 60% alcohol.

Test Results

You will be contacted with your results.

If you test positive on a diagnostic test for the virus, you must continue isolation. You will get a call from a public health representative to identify any contacts you have had.

If you test negative, but you have been in close contact with a person known to have been infected, you must still continue quarantine until 14 days have passed from your last contact with a person known to have COVID-19. Even though you may feel well now, you are at risk of getting the disease and you may get sick. It can take up to 14 days to get the disease.

Your local health department can help you determine when it is safe to stop isolation or quarantine. Find them at www.nysacho.org/directory

Learn more at coronavirus.health.ny.gov

Support and Job Assistance

Any New Yorker under a mandatory or precautionary order to stay home may be eligible for job-protected sick leave and compensation. Learn more at https://coronavirus.health.ny.gov/protecting-public-health-all-new-porkers#employee

If you need help caring for yourself or your children while in isolation or quarantine, call your local health department. Find them at www.nysacho.org/directory

Stay apart now. Be together later.

13112

New York State Department of Health

Over -



Department of Health

Contact Tracing Tool for People Being Tested for COVID-19

If you test positive for COVID-19, you will get a call from a public health representative to identify any contacts you
have had. This form can help you identify your contacts so you will be ready for the call.

1 If you hav				
Include p		our home, and peo	our contact tracing date? ple who may have visited like friend:	s, a babysitter or anyone else
1 2 3	ame of Person		Date Last in I	Home Their Phone Number
5	ist of what you did	l oach day since yo	ur contact tracing date with as muc	th detail as possible
Include th	nings like hanging	out with neighbors,	going to work, running errands, appoi plic transportation to get there. Use a	intments, social or recreational
Day One:	Location	Name	People you were with Address	Phone Number
Day Two:			People you were with	
Activity	Location	Name	Address	Phone Number
Day Three:			People you were with	
Activity	Location	Name	Address	Phone Number
Day Four:			People you were with	
Activity	Location	Name	Address	Phone Number
13114		New York S	tate Department of Health	5/20

To order materials from NYSDOH:

bmcc@health.ny.gov

Available in Spanish

NYSDOH Contact Tracing Tool



For Their Contacts

To order materials from NYSDOH:

bmcc@health.ny.gov



You're a part of the solution... now answer the phone!



You've stayed home!



You're wearing masks!



Now, answer the phone!

As we battle coronavirus together, tracing exposures to COVID is important to stop the spread.

The NYS Contact Tracing Program works with confirmed positive COVID-19 people to determine who they have been in contact with. Trained specialists reach out to those contacts about possible exposure. If you have been identified as a contact you will get a call from "NYS Contact Tracing."

Because the disease can be transmitted without symptoms, notifying people about a possible exposure is critical to stop the spread.

So, if you get a call from "NYS Contact Tracing" please answer. It is confidential and private.

Please Answer the Phone

so we can keep NY moving forward and stop the spread of COVID-19.

health.ny.gov/coronavirus

13135

5/20



NYSDOH COVID-19 Testing Resources

SARS-CoV-2 Diagnostic Testing



What is SARS-CoV-2?

SARS-CoV-2 stands for Severe Acute Respiratory Syndrome Coronavirus Type 2, which is the name of the virus causing the current COVID-19 public health emergency.

What are the symptoms of COVID-19?

Symptoms of COVID-19 may include fever, cough, shortness of breath or difficulty breathing. Other symptoms have been reported including chills, muscle aches, headache, sore throat, abdominal pain, vomiting, diarrhea. runny nose, fatigue, wheezing, and new loss of taste or smell. Some people with COVID-19 develop symptoms and some do not. Both symptomatic and asymptomatic individuals can transmit COVID-19 to others. Talk to your health care provider if you have any of these symptoms.

How do I know if I am infected with SARS-CoV-2?

Diagnostic tests detect SARS-CoV-2 in samples collected from your nose or throat. A diagnostic test is the only way to know if you are infected with SARS-CoV-2. These tests can be performed for those with or without

How does the SARS-CoV-2 diagnostic test work?

The test uses a technique called Polymerase Chain Reaction (PCR) to determine if genetic material from the virus is present in the sample collected. If there is no SARS-CoV-2 virus present in the sample, then no genetic material

My report says I have a positive result. What does that mean?

This means you have SARS-CoV-2 (COVID-19). You should consult with your health care provider, who will monitor your symptoms and provide guidance about how your illness should be managed. It is important to understand that, if you are infected with SARS-CoV-2, you may transmit the virus to others. You should follow NYSDOH guidance about isolation and physical distancing.

My report says I have a negative result. What does that mean?

A negative test result means that SARS-CoV-2 was not detected in your sample. However, a negative result does not guarantee that you are not infected. If you continue to feel unwell or develop symptoms resembling those of COVID-19, you should isolate yourself and ask your health care provider if you should be tested again. If you had close contact with someone known to have COVID-19, you should remain in quarantine for 14 days after exposure, even if you had a negative test result.

My report says I have an inconclusive or indeterminant result. What does

This means that the test was not able to determine whether SARS-CoV-2 was or was not present. Talk to your health care provider, as they may decide you should be tested again.

For more information on COVID-19 in NYS go to: https://health.ny.gov/coronavirus

New York State Department of Health



HOWARD A. ZUCKER, M.D., J.D.

SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

Clinical Laboratories, Limited Service Labs, Healthcare Providers, Healthcare Facilities, and Local Health Departments

NYS Department of Health (Department) Bureau of Surveillance and Data Systems (BSBS)

Health Advisory: COVID-19 Serology Testing

Background

Serological tests for determining the presence of antibodies against SARS-CoV-2 are now available from commercial manufacturers. Serology tests are used to determine if antibodies against SARS-CoV-2 are present. Certain serology tests can look for the general presence of SARS-CoV-2 antibodies, while others can determine if specific types of SARS-CoV-2 antibodies, such as IgM and/or IgG, are present.

FDA and Serological Testing

The US Food and Drug Administration (FDA) is allowing commercial manufacturers of COVID-19 serology tests to distribute these tests to laboratories once they notify the FDA that they have validated their test. A list of manufacturers that have notified the FDA can be found at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/fags-diagnostic-

Although there are manufacturers that have notified the FDA that their tests have been validated, and the FDA has approved the distribution of the tests, the data demonstrating the accuracy and reliability of the tests has not been reviewed by the FDA. In addition, these tests have not necessarily been granted approval under the FDA's Emergency Use Authorization (EUA) process. Tests being distributed prior to the approval under the FDA's EUA process can only be performed by laboratories approved to conduct high complexity testing. These tests are not considered waived and, therefore, cannot be used at the point of care

Laboratories using COVID-19 serological tests from these commercial manufacturers are required to include specific disclaimers when issuing test results, including the following:

- . This test has not been reviewed by the FDA.
- . Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- . Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Empire State Plaza, Coming Tower, Albany, NY 12237 | health.ny.gov

NYSDOH Health Advisory on COVID-19 Serologic Assays





- New Yorkers without health insurance can apply through NY State of Health through <u>July 15th, 2020</u>
- Must apply within 60 days of losing coverage



Questions or Concerns

- Call the local health department <u>www.health.ny.gov/contact/contact_information/</u>
- In New York City: Notify the NYC DOHMH provider access line (PAL)
 - 1-866-NYC-DOH1 or 1-866-692-3641 (works 24 hours/day x 7 days/week)
- Providers who are unable to reach the LHD can contact the NYSDOH Bureau of Communicable Disease Control at 518-473-4439 during business hours or the NYSDOH Public Health Duty Officer at 1-866-881-2809 evenings, weekends, and holidays



QUESTIONS?

TO NYS' HEALTHCARE PROVIDERS THANK YOU!

